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**Revisions to Joint Commission Standards
in Support of Patient Safety and Medical/Health Care Error(1)Reduction**

January, 2001

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Note that new language appears in un-italicized typeface. Language that appears in *italics* is existing standards language and is included as context.

Introduction to Patient Safety and Medical/Health Health Care Errors Reduction Standards

Standards throughout this Manual are designed to improve patient safety and reduce risk to patients. Recognizing that effective medical/health care error reduction requires an integrated and coordinated approach, the following standards relate specifically to leadership's role in an organization-wide safety program that includes all activities within the organization which contribute to the maintenance and improvement of patient safety, such as performance improvement, environmental safety, and risk management. The standards do not require the creation of new structures or "offices" within the organization; rather, the standards emphasize the need to integrate all patient-safety activities, both existing and newly created, with an identified locus of accountability within the organization's leadership.

Although the standards focus on patient safety, it would be difficult to create an organization-wide safety initiative that excludes staff and visitors. Further, many of the activities taken to improve patient safety (e.g., security, equipment safety, infection control) encompass staff and visitors as well as patients.

Effective reduction of medical/health care errors and other factors that contribute to unintended adverse patient outcomes in a health care organization requires an environment in which patients, their families, and organization staff and leaders can identify and manage actual and potential risks to patient safety. This environment encourages recognition and acknowledgment of risks to patient safety and medical/health care errors; the initiation of actions to reduce these risks; the internal reporting of what has been found and the actions taken; a focus on processes and systems; and minimization of individual blame or retribution for involvement in a medical/health care error. It encourages organizational learning about medical/health care errors and supports the sharing of that knowledge to effect behavioral changes in itself and other health care organizations to improve patient safety. The leaders of the organization are

responsible for fostering such an environment through their personal example and by establishing mechanisms that support effective responses to actual occurrences; ongoing proactive reduction in medical/health care errors; and integration of patient safety priorities into the new design and redesign of all relevant organization processes, functions, and services.

Leadership Chapter

Standard
LD.5
The leaders ensure implementation of an integrated patient safety program throughout the organization.

Intent of LD.5
The patient safety program includes at least the following:

- Designation of one or more qualified individuals or an interdisciplinary group to manage the organization-wide patient safety program. Typically these individuals may include directors of performance improvement, safety officers, risk managers, and clinical leaders.
- Definition of the scope of the program activities, that is the types of occurrences to be addressed--typically ranging from "no harm" frequently occurring "slips" to sentinel events with serious adverse outcomes.
- Description of mechanisms to ensure that all components of the health care organization are integrated into and participate in the organization-wide program.
- Procedures for immediate response to medical/health care errors, including care of the affected patient(s), containment of risk to others, and preservation of factual information for subsequent analysis.
- Clear systems for internal and external reporting of information relating to medical/health care errors.
- Defined mechanisms for responding to the various types of occurrences, e.g., root cause analysis in response to a sentinel event, or for conducting proactive risk reduction activities.
- Defined mechanisms for support of staff who have been involved in a sentinel event.
- At least annually, a report to the governing body on the occurrence of medical/health care errors and actions taken to improve patient safety, both in response to actual occurrences and proactively.

Standard
LD.5.1
Leaders ensure that the processes for identifying and managing sentinel events (2), are defined and implemented.

Intent of LD.5.1
When a sentinel event occurs in a health care organization, it is necessary that appropriate individuals within the organization be aware of the event; investigate and understand the causes that underlie the event; and make changes in the organization's systems and processes to reduce the probability of such an event

in the future. The leaders are responsible for establishing processes for the identification, reporting, analysis, and prevention of sentinel events and for ensuring the consistent and effective implementation of a mechanism to accomplish these activities including:

- *Determination of definitions of sentinel event and near misses(3), which are approved by the leaders and communicated throughout the organization; at a minimum, the organization's definition of sentinel event must include those events that are subject to review under the Joint Commission's Sentinel Event Policy as published in this manual;*
- *Creation of process for reporting of sentinel events through established channels within the organization and, as appropriate, to external agencies in accordance with law and regulation;*
- *Creation of a process for conducting a thorough root cause analysis which focuses on process and system factors, with an associated risk reduction plan;*
- *Documentation of a risk-reduction strategy and action plan that includes measurement of the effectiveness of process and system improvements to reduce risk.*

Standard
LD.5.2
Leaders ensure that an ongoing, proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented.

Intent of LD.5.2
The organization seeks to reduce the risk of sentinel events and medical/health care system error-related occurrences by conducting its own proactive risk assessment activities and by using available information about sentinel events known to occur in health care organizations that provide similar care and services. This effort is undertaken so that processes, functions and services can be designed or redesigned to prevent such occurrences in the organization.

Proactive identification and management of potential risks to patient safety have the obvious advantage of *preventing* adverse occurrences, rather than simply *reacting* when they occur. This approach also avoids the barriers to understanding created by hindsight bias and the fear of disclosure, embarrassment, blame, and punishment that can arise in the wake of an actual event.

Leaders provide direction and resources to conduct the following proactive activities to reduce risk to patients:

- At least annually, select at least one high-risk process for proactive risk assessment, such selection to be based, in part, on information published periodically by the Joint Commission that identifies the most frequently occurring types of sentinel events and patient safety risk factors;
- Assess the intended and actual implementation of the process to identify the steps in the process where there is, or may be, undesirable variation (i.e., what engineers call potential "failure modes");

- For each identified "failure mode" identify the possible effects on patients (what engineers call the "effect"), and how serious the possible effect on the patient could be (what engineers call the "criticality" of the effect);
- For the most critical effects, conduct a root cause analysis to determine why the variation (the failure mode) leading to that effect may occur;
- Redesign the process and/or underlying systems to minimize the risk of that failure mode or to protect patients from the effects of that failure mode;
- Test and implement the redesigned process;
- Identify and implement measures of the effectiveness of the redesigned process; and
- Implement a strategy for maintaining the effectiveness of the redesigned process over time.

Standard
LD.5.3
Leaders ensure that patient safety issues are given a high priority and addressed when processes, functions, or services are designed or redesigned.

Intent of LD.5.3
When processes, functions, or services are designed or redesigned, information from within the organization and from other organizations about potential risks to patient safety, including the occurrence of sentinel events, is considered and, where appropriate, used to minimize the risk to patients affected by the new or redesigned process, function, or service.

Other Leadership Standards Relevant to Patient Safety and Medical/Health Care Error Reduction

Standard
LD.1.4
The planning process provides for setting performance-improvement priorities and identifies how the hospital adjusts priorities in response to unusual or urgent events.

Intent of LD.1.4
The planning process provides the framework or criteria for establishing performance improvement priorities. The planning process gives priority consideration to:

- *Processes that affect a large percentage of patients;*
- *Processes that place patients at risk if not performed well, if performed when not indicated, or if not performed when indicated; and*
- *Processes that have been or are likely to be problem-prone.*

The hospital's priority setting is sensitive to emerging needs such as those identified through data collection and assessment, unanticipated adverse occurrences affecting patients*, changing regulatory requirements, significant*

patient and staff needs, changes in the environment of care, or changes in the community.

Standard
LD.1.8
The leaders and other relevant personnel collaborate in decision making.

Intent of LD.1.8
The hospital's leaders and directors of relevant departments collaborate in:

- *Development of hospital-wide patient care programs, policies, and procedures that describe how patients' care needs are assessed and met;*
- *Development and implementation of the hospital's plan for providing patient care;*
- *Decision-making structures and processes; and*
- *Implementation of an effective and continuous program to measure, assess, and improve performance* and improve patient safety.

Standard
LD.3.2
The leaders foster communication and coordination among individuals and departments.

Intent of LD.3.2
To coordinate and integrate, patient care and to improve patient safety, *the leaders develop a culture that emphasizes cooperation and communication. An open communication system facilitates an interdisciplinary approach to providing patient care. The leaders develop methods for promoting communication among services, individual staff members, and less formal structures such as quality action teams, performance-improvement teams, or members of standing committees.*
This leadership role is commonly referred to as coaching.

Standards
LD.3.4
All departments develop policies and procedures in collaboration with associated departments.

LD.3.4.1 The leaders provide for mechanisms to measure, analyze, and manage variation in the performance of defined processes that affect patient safety.

Intent of LD.3.4.1
Inconsistency in the performance of processes, as intended by their design and described in organization policies and procedures, frequently leads to unanticipated and undesirable results. In order to minimize risk to patients due to such variation, the leaders ensure that the actual performance of processes identified as error-prone or high-risk regarding patient safety is measured and analyzed, and when significant variation is identified, appropriate corrective actions are taken to enhance the system(s).

At any given time, the performance of critical steps in at least one high-risk process is the subject of ongoing measurement and periodic analysis to determine the degree of variation from intended performance.

Standards
LD.4.4
The leaders allocate adequate resources for measuring, assessing, and improving the hospital's performance and for improving patient safety.

LD.4.4.1 *The leaders assign personnel needed to participate in performance-improvement activities* and activities to improve patient safety.

LD.4.4.2 *The leaders provide adequate time for personnel to participate in performance-improvement activities* and activities to improve patient safety.

LD.4.4.3 *The leaders provide information systems and data management processes for ongoing performance improvement* and improvement of patient safety.

LD.4.4.4 *The leaders provide for staff training in the basic approaches to and methods of performance improvement* and improvement of patient safety.

LD.4.4.5 The leaders assess the adequacy of their allocation of human, information, physical, and financial resources in support of their identified performance improvement and safety improvement priorities.

Intent of LD.4.4 Through LD.4.4.5
Hospital leaders provide adequate human resources for these activities and give these staff sufficient time and support to be effective. Appropriate staff members are assigned in sufficient numbers to ensure progress in the pursuit of improvement and risk-reduction priorities. *Leaders allow enough time for performance-improvement activities* and activities to improve patient safety, *and provide needed information and technical assistance. Each department determines what resources are sufficient for its improvement efforts* and activities to improve patient safety.

Standard
LD.4.5
The leaders measure and assess the effectiveness of their contributions to improving performance and improving patient safety.

Intent of LD.4.5
The performance-improvement framework in the "Improving Organization Performance" chapter is used to design, measure, assess, and improve the leaders' performance and contribution to performance improvement and improvement in patient safety. The leaders

- *set measurable objectives for improving hospital performance* and improving patient safety;
- *gather information to assess their effectiveness in improving hospital performance* and in improving patient safety;

- *use pre-established, objective process criteria to assess their effectiveness in improving hospital performance* and in improving patient safety;
- *draw conclusions based on their findings and develop and implement improvement in their activities; and*
- *evaluate their performance in supporting sustained improvement.*

Improving Organization Performance Chapter

Standard
PI.2
New or modified processes are designed well.

Intent of PI.2
When processes, functions, or services are designed well, they draw on a variety of information sources. Good process design

a. *is consistent with the organization's mission, vision, values, goals and objectives, and plans;*
b. *meets the needs of individuals served, staff, and others;*
c. *is clinically sound and current (for instance, use of practice guidelines, successful practices, information from relevant literature, and clinical standards);*
d. *is consistent with sound business practices;*
e. *incorporates available information from* within the organization and *from other organizations about* potential risks to patients, *including the occurrence of sentinel events* in order to minimize risks to patients affected by the new or redesigned process, function, or service;
f. includes analysis and/or pilot testing to determine whether the proposed design/redesign is an improvement; and
g. *incorporates the results of performance-improvement activities.*

The organization incorporates information related to these elements, when available and relevant, in the design or redesign of processes, functions, or services.

Standard
PI.3.1
The organization collects data to monitor its performance.

Intent for PI.3.1
Performance monitoring and improvement are data driven. The stability of important processes can provide the organization with information about its performance. Every organization must choose which processes and outcomes (and thus which types of data) are important to monitor based on its mission and the scope of care and services it provides. The leaders prioritize data collection based on the organization' mission, care and services provided, and populations served (see LD.4.2 for priority setting). **Data that the organization considers for collection to monitor performance include the following:**

- *Performance measures related to accreditation and other requirements;*
- *Risk management;*
- *Utilization management;*
- *Quality control;*
- **Patient, family, and staff opinions, needs, perceptions of risks to patients, and suggestions for improving patient safety;**
- **Staff willingness to report medical/health care errors;**
- *Behavior management procedures, if used;*
- *Outcomes of processes or services;*
- *Autopsy results, when performed;*
- *Performance measures from acceptable databases;*
- *Customer demographics and diagnoses;*
- *Financial data;*
- *Infection control surveillance and reporting;*
- *Research data; and*
- *Performance data identified in various chapters of this manual.*

Organizations are required to collect data about the needs, expectations, and satisfaction of individuals and organizations served; Individuals served and their family members can provide information that will give an organization insight about process design and functioning. The organization asks them about

- *their specific needs and expectations;*
- *their perceptions of how well the organization meets these needs and expectations;*
- *how the organization can improve;* and
- **how the organization can improve patient safety.**

Standard
PI.4.3
Undesirable patterns or trends in performance and sentinel events are intensively analyzed.

Intent of PI.4.3
When the organization detects or suspects significant undesirable performance or variation, it initiates intense analysis to determine where best to focus changes for improvement. The organization initiates intense analysis when the comparisons show that

- *levels of performance, patterns, or trends vary significantly and undesirably from those expected;*
- *performance varies significantly and undesirably from that of other organizations;*
- *performance varies significantly and undesirably from recognized standards; or*
- *when a sentinel event has occurred.*

When monitoring performance of specific clinical processes, certain events always elicit intense analysis. Based on the scope of care or services provided, intense analysis is performed for the following:

- *Confirmed transfusion reactions;*
- *Significant adverse drug reactions; and*
- *Significant medication errors and* hazardous conditions.(4)

Intense analysis should also occur for those topics chosen by the leaders as performance-improvement priorities and priorities for proactive reduction in patient risk (see LD.1.4 and LD.4.4.2), *or when undesirable variation occurs that changes the priorities. Intense analysis involves studying a process to learn in greater detail about how it is performed or how it operates*, how it can malfunction and how errors occur.

A root cause analysis is performed when a sentinel event occurs.

An intense analysis is also performed for the following:

- *Major discrepancies, or patterns of discrepancies, between preoperative and postoperative (including pathologic) diagnoses, including those identified during the pathologic review of specimens removed during surgical or invasive procedures; and*
- *Significant adverse events associated with anesthesia use.*

Standard
PI.4.4 *The organization identifies changes that will lead to improved performance* and improve patient safety.

Intent of PI.4.4
The organization uses the information from the data analysis to identify system changes that will improve performance or improve patient safety. Changes are identified based on the analysis of data from targeted study or from analysis of data from ongoing monitoring. A change is selected, and the organization plans to implement the change on a pilot test basis or across the organization. Performance measures are selected that help determine the effectiveness of the change and whether it resulted in an improvement (see PI.3.1.1, PI.3.1.2, and PI.3.1.3) once the change is implemented.

Management of Information Chapter

Standard
IM.1 *The hospital plans and designs information-management processes to meet internal and external information needs*.

Intent of IM.1
A comprehensive needs assessment considers the following questions, as appropriate:

- What are the barriers to effective communication among caregivers?

Standards
IM.5
Transmission of data and information is timely and accurate.

IM.5.1 *The format and methods for disseminating data and information are standardized, whenever possible.*

Intent of IM.5 and IM.5.1
Internally and externally generated data and information are accurately transmitted to users. The integrity of data and information is maintained, and there is adequate communication between data users and suppliers. Specific attention is directed to the processes for ensuring accurate, timely, and complete verbal and written communication among care givers and all others involved in the utilization of data. *The timing of transmission is appropriate to the data's intended use.*

The format and methods of disseminating internal data and information are tailored to the needs of users and the hospital. Dissemination methods and formats provide for easy retrieval. The means by which data and information are exchanged is standardized whenever possible to facilitate interpretation.

Standard
IM.7.2
The medical record contains sufficient information to identify the patient, support the diagnosis, justify the treatment, document the course and results, and promote continuity of care among health care providers.

Intent of IM.7 Through IM.7.2
The environment in which patient-specific information is provided supports timely, accurate, secure, and confidential recording and use of patient-specific information. The system recalls historical patient data and is able to furnish data about current encounters. To facilitate consistency and continuity in patient care, the medical record contains very specific data and information, including

- Test results relevant to the management of the patient's condition;

Standard
IM.8
The hospital collects and analyzes aggregate data to support patient care and operations.

Intent of IM.8
The hospital aggregates and analyzes clinical and administrative data to support

- *patient care;*
- *decision making;*
- *management and operations;*
- *analysis of trends over time;*
- *performance comparisons over time and with other organizations;*
- *performance improvement*; and

- reduction in risks to patients.

The hospital is able to aggregate the following data and information:

a. *Pharmacy transactions, as required by law and to control and account for all drugs;*
b. *Information about hazards and safety practices used to identify safety management issues to be addressed by the organization;*
c. *Records of radionuclides and radiopharmaceuticals, including the radionuclide's identity, the date received, method of receipt, activity, recipient's identity, date administered, and disposal;*
d. *Records of required reporting to authorities;*
e. *Performance measures of processes and outcomes;*
f. *Summaries of performance-improvement actions and actions to reduce risks to patients;*

Standard
IM.9
The hospital provides systems, resources, and services to meet its needs for knowledge-based information in patient care, education, research, and management.

Intent of IM.9
Knowledge-based information, often referred to as "literature," includes journal literature, successful practices, reference information, and research data. It may be found in a variety of forms, including articles, abstracts, or indexes in print or electronic format (see "Internet Resources" preceding "Suggested Readings and Other Resources" in this chapter); recent editions of texts, periodicals, and other professional resources; and patient education materials that meet individual and organizational needs. Knowledge-based information is authoritative and up-to-date. It supports clinical and management decision making, performance-improvement activities, patient and family education, continuing education of staff, and research.

This standard addresses the hospital's ability to provide knowledge-based information to those who need it. A hospital's need for knowledge-based information can be met in a variety of ways, including an on-site library department or unit, the services of a qualified medical librarian on site, or a variety of other cooperative arrangements for providing similar services to effectively meet the knowledge-based information needs of the institutions. These services may be shared with other hospitals or community resources, as long as needed information is easily accessible to hospital staff.

Appropriate knowledge-based information is acquired, assembled, and transmitted to users. Knowledge-based information management consists of systems, resources, and services to

- *help health professionals acquire and maintain the knowledge and skills they need to care for patients;*
- *support clinical and management decision making;*

- *support performance improvement* and activities to reduce risk to patients;
- *satisfy research-related needs; and*
- *educate patients and families.*

Patient Rights and Organization Ethics Chapter

Standard
RI.1.2.2
Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.

Intent of RI.1.2.2
The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes.

Education Chapter

Standards
PF.1.3
Patients are educated about the safe and effective use of medication, according to law and their needs.

PF.1.4
Patients are educated about the safe and effective use of medical equipment.

PF.1.5
Patients are educated about potential drug-food interactions, and provided counseling on nutrition and modified diets.

PF.1.10
The hospital makes clear to patients and families that the patient is an integral member of the health care team, describes *what their responsibilities are regarding the patient's ongoing health care needs, and gives them the knowledge and skills they need to carry out their responsibilities.*

Intent of PF.1.10
The safety of health care delivery is enhanced by the involvement of the patient, as appropriate to his/her condition, as a partner in the health care process. In addition, *hospitals are entitled to reasonable and responsible behavior on the part of patients and their families --always keeping in mind, of course, the nature of the illness and the constraints it imposes. To facilitate such behavior, hospital staff members clearly identify for patients and families what their responsibilities are, and educate them accordingly.* Specific attention is directed at educating patients and families about their role in helping to facilitate the safe delivery of care. *Hospital policies and procedures make clear how and by whom this is done.*

Patient responsibilities generally include at least the following:

- Providing information. The patients and family are responsible for providing, to the best of their knowledge, accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to the patient's health. They are responsible for reporting perceived risks in their care and unexpected changes in the patient's condition to the responsible practitioner.
- Asking questions. The patient and family are responsible for asking questions when they do not understand what they have been told about the patient's care or what they are expected to do.

Continuum of Care Chapter

Standards
CC.4
The hospital ensures continuity over time among the phases of service to a patient.

CC.5
The hospital ensures coordination among the health professionals and services or settings involved in a patient's care.

Intent of CC.4 and CC.5
Care is coordinated throughout

- *entry;*
- *assessment;*
- *diagnosis;*
- *planning;*
- *treatment; and*
- *transfer or discharge.*

Throughout all phases, patient needs are matched with appropriate resources within the continuum (for example, special care units, skilled nursing facility, or community services). Transitions between levels of care are smooth. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation or referral, primary physician care, or other follow up. Communication and transfer of information between and among the health care professionals is essential to a seamless, safe, and effective process.

Management of Human Resources Chapter

Standard
HR.4
An orientation process provides initial job training and information and assesses the staff's ability to fulfill specified responsibilities.

Intent of HR.4
The orientation process assesses each staff member's ability to fulfill specific responsibilities. The process familiarizes staff members with their jobs and with

the work environment before the staff begins patient care or other activities. In this way, the process promotes safe and effective job performance. The orientation process emphasizes specific job-related aspects of patient safety. *When the hospital uses volunteer services, volunteers are oriented to patient care, safety, infection control, and any other activities they are expected to perform competently.*

Standard
HR.4.2
Ongoing in-service and other education and training maintain and improve staff competence and support an interdisciplinary approach to patient care.

Intent of HR.4.2
The hospital ensures that each staff member participates in ongoing in-service education and other training to increase his or her knowledge of work-related issues. Ongoing in-service and other education and training programs emphasize specific job-related aspects of patient safety. As appropriate, this training incorporates methods of team training to foster an interdisciplinary, collaborative approach to the delivery of patient care, and reinforces the need and way(s) to report medical/health care errors. *The hospital periodically reviews the staff's abilities to carry out job responsibilities, especially when introducing new procedures, techniques, technology, and equipment. Ongoing in-service and other education and training programs are appropriate to patient age groups served by the hospital.*

1. Error. An unintended act, either of omission or commission, or an act that does not achieve its intended outcome.
2. Sentinel Event. An unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
3. Near Miss. Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome. Such a near miss falls within the scope of the definition of a sentinel event, but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.
4. Hazardous Condition. Any set of circumstances (exclusive of the disease or condition for which the patient is being treated) which significantly increases the likelihood of a serious adverse outcome.